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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,418	08/20/2003	Bob G. Sanders	D6150CIP/D	6977

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EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,418	SANDERS ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,14-20 and 26-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,14-20 and 26-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's amendment submitted February 1, 2007 wherein claims 1, 2, 8, 20, 26, 27, 31, 49, 58, and 76 are amended. This application is a divisional application of 09/502592, now US patent 6770672, filed February 11, 2000, which is a continuation in part of 09/404001, now US patent 6417223, filed September 23, 1999, which claims priority to provisional application 60/101542, filed September 23, 1998..

Claims 1-8, 14-20, and 26-84 are pending in this application.

Claims 1-8, 14-20, and 26-84 as amended are examined on the merits herein.

Applicant's amendment submitted February 1, 2007, with respect to the rejection of instant claims 1, 3-8, 26, 28, 31-33, 35, 37, 39, 41, 49, 52, 54, 56, 58-60, 62, 64, 66, 68, 76, 79, 81, and 83 under 35 USC 112, first paragraph for lacking written description for a method involving a compound wherein R4 is hydrogen, has been fully considered and found to be persuasive to remove the rejection as the claims as amended do not include compounds where R4 is hydrogen. Therefore the rejection is withdrawn.

The following rejections, of record in the previous office action, are maintained:

Claim Rejections - 35 USC § 112 – 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 14-20 and 26-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of colon and prostate cancer in a patient in need thereof, does not reasonably provide enablement for the general treatment of cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims without undue experimentation.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);
(2) The amount of direction or guidance presented;
(3) The presence or absence of working examples of the invention;
(4) The nature of the invention;
(5) The state of the prior art;
(6) The relative skill of those in the art;
(7) The predictability or unpredictability of the art; and
(8) The breadth of the claims.

The claims are drawn to methods of cell proliferative disease wherein the method is currently restricted to the treatment of neoplastic disease. The treatment of neoplastic disease comprises the treatment of all cancer, which encompasses a vast range of diseases. Furthermore, although the skill level in this art would be high, it remains the fact that many types of cancer remain intractable.

The examiner notes that Applicant has disclosed *in vitro* data tabulated for a number of compounds with a number of cell lines. However, out of 32 compounds in the table, 14 of them are disclosed as having no activity and/or not tested. Furthermore, of the ones that are tested, the effectiveness is sporadic. Applicant does have animal testing for breast, colon and prostate cancer. The results for colon and prostate appear

to be comparable to accepted treatments for these diseases. However, the effectiveness in breast cancer appears to be much less than taxol, so it is not clear that these data support effectiveness for the treatment of this disease. Additionally, cell line testing is not a reliable guide for *in vivo* treatment since such testing has historically failed to produce a number of compounds having a wide spectrum of tumor activity. As Monks (Anti-Cancer Drug Design, 1997) teaches, "mere detection of anti-proliferative activity is not enough to engender excitement." Even after the filing date of the instant application, broad extrapolation of *in vitro* testing to *in vivo* effectiveness remains problematic. See for example Balis (JNCI, 2002). Even determining the appropriate animal model is not routine. See for example Kerbel (Cancer and Metastasis, 1999). For the reasons set forth above, it appears that one of ordinary skill would require undue experimentation in order to use the present invention commensurate with the scope set forth in the instant claims.

Response to Argument: Applicant's arguments, submitted February 1, 2007, with respect to the above grounds of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the level of skill in the art and the amount of description disclosed in Applicant's invention are sufficient to enable one skilled in the art to practice the claimed invention absent undue experimentation. However, the breadth of the claims and the exceptional unpredictability of the cancer art when considered as a whole are such that an extremely high level of skill and detailed description would be required to extrapolate from the few examples provided to all cancers in existence.

Applicants argue that the specification demonstrates that the claimed compounds are useful for inhibiting growth and inducing apoptosis in a wide variety of cancer cells. However, as discussed in the original office action, the effectiveness of most compounds tested is sporadic. Furthermore, the 22 cell lines tested are breast, cervical, ovarian, prostate, lung, and lymphoid cancer cell lines. No data is provided for other types of cancers cell lines such as leukemias, bone cancers, renal cancers, melanomas, or neurological cancers, for example. In addition to the raw number of examples provided, the scope covered by the examples must be considered as well in determining whether the examples are sufficient to provide broad enablement for a generic class of diseases.

With respect to the disclosure of various screening methods, *in vivo* animal testing is in fact generally required to provide enablement for **cancer** treatment in view of the exceptional level of unpredictability of this art. As discussed in the previous office action, it has been established in the art that mere demonstration of growth-inhibitory or cytotoxic activity of a compound against a number of different tumor cell lines does not thereby enable one skilled in the art to treat all cancers.

For these reasons, Applicant's arguments are not found persuasive and the rejection is made **FINAL**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claims because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 14-20 and 26-84 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-16 of U.S. Patent No. 6,645,998.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of '998 recite the treatment of cell proliferative disorders, including neoplastic disease by the administration of a genus of compounds encompassed by the genus used in the instant method. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select cancer from the claimed cell proliferative disorders and use any of the species recited in the claims to administer for treatment thereof.

Response to Argument: In the response submitted February 1, 2007, Applicant states that a terminal disclaimer will be submitted upon indication of allowable subject matter. As no terminal disclaimer has been submitted, the rejection is maintained and made **FINAL.**

Claims 1-8, 14-20 and 26-84 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-65 of copending Application No. 10/695,275. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '275 recite a method for inhibiting the growth of tumor cells by administration of a genus of compounds encompassed by the instant claims. The use of any of the recited species would anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Argument: In the response submitted February 1, 2007, Applicant states that a terminal disclaimer will be submitted upon indication of allowable subject matter. As no terminal disclaimer has been submitted, the rejection is maintained and made **FINAL.**

Conclusion

No claims are allowed in this application. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LEIGH C. MAIER
PRIMARY EXAMINER